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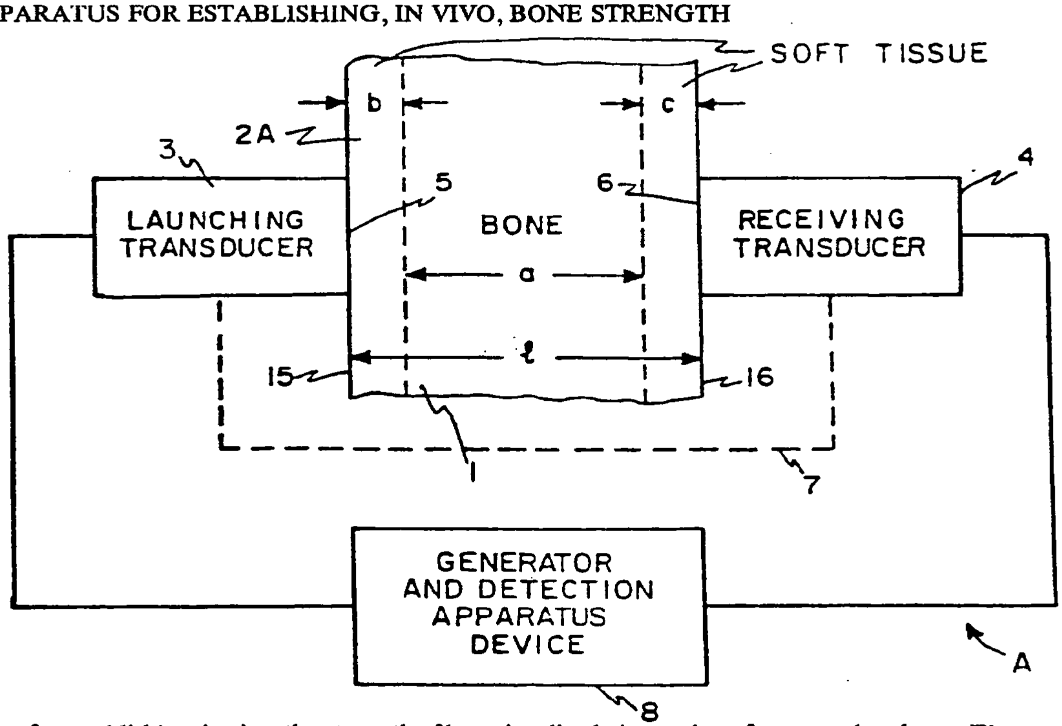

(57) Abstract

A system for establishing, in vivo, the strength of bone in a live being such as, for example, a horse. The system permits determination of the speed of travel of sound through the bone and the strength of the bone is assessed on the basis of said speed of travel. Changes in the strength due to continual cycling in the fatigue zone which can eventually lead to fracture are measured with a launching transducer (3) placed on one side of the leg to pass ultrasonic waves through the tissue and bone to a receiving transducer (4). The distance between the two transducers is measured by an element (7) and the speed of travel of sound through the bone is detected by the generator and detection apparatus (8).

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APPARATUS FOR ESTABLISHING, IN VIVO, BONE STRENGTH

The present invention relates to mechanisms for determining the strength of bone and the condition of tendons and ligaments of a live being.

In the explanation that follows, most attention is directed to the study of horses, particularly since work leading to the present invention was done in connection with horses.

When bone is stressed in a succession of load-unload cycles an accumulation of microscopic damage occurs if the peak load per unit area is sufficiently high. Chamay (A. Chamay, J. Biomechanics 3, 263 (1970)) has described this process as repeated strain in the "fatigue zone". Slow bone deformation is observed, the bone not returning after unloading at the end of a cycle to its precise condition at the start of the cycle. Continual cycling in the fatigue zone eventually leads to fracture. This accumulation of internal damage is not unlike that taking place in a piece of metal when it is bent back and

forth or flexed repeatedly. Micro-crushing and micro-fracturing occurs in bone in the process of absorbing shock. Given a period of rest the body restores the strength of bone in a remodeling process. It is important to understand that the bones in the skeletal structure that are subjected to large stresses are constantly going through fatigue weakening on the one hand and restoration by remodeling on the other.

The present invention is primarily concerned with a way of noninvasively determining the strength of bone in a live animal. The race horse in particular subjects his legs to very large stresses in the course of training and competition. Of every 1000 horses starting races, between three and six horses will suffer a fracture and many of these animals will have to be destroyed. This represents an unfortunate loss of animal life and in many cases a severe economic loss. Although a horse may come out of a race in outwardly fine shape, there has been no method of accurately gauging how much subtle wear and tear has taken place. These problems of the horse are shared by other quadrupeds such as the racing greyhound dog and, of course, man himself.

It has been found and is herein disclosed that the strength of bone can be monitored by measuring the velocity of sound through the bone. As bone is weakened by repeated load cycling, it has been discovered that the velocity of sound continually decreases. Experiments have been carried out on the third metacarpal bone freshly removed from the leg of a horse. This work is described in a thesis "Preventive Diagnosis of Breakdown" by Kelvin O'Kamura (MIT library 1979) which was done under the present inventor's supervision. This disclosure takes these in-vitro experiments and extends the technique to bone in the living animal where the complication of surrounding soft tissue must be dealt with.

Typical values of the velocity of sound at 0.5 x 10^6 Hz before load cycling were 2850 m/sec at the distal end, 3140 m/sec across the midshaft, and 2600 m/sec across the proximal end. Sample bones were load cycled using a Materials Testing Service (MTS) computer controlled hydraulic press. The computer controlling the action of the machine was programmed to apply a load to the cannon bone of a horse (McIII) as a function of time in a manner that simulates the actual load cycle of the race horse in competition. The velocity of sound was measured across distal, midshaft, and proximal regions. It was found that the velocity of sound continually decreases as a result of cycling. The load cycling process ultimately produces a fracture of the bone. It was observed that the velocity of sound suffered the largest decrease in the region where the fracture later occurred. A drop in the velocity of sound of approximately 10% was found to take place due to the load cycling in the region of eventual fracture.

A linear relation between the elastic modulus E of horse and the density of ρ has been published by H. F. Schryver (Am. Journal of Vet. Res. 35, 25 (1978)) in the form

$$E = E_0 + E_1\rho .$$

Schryver further has published a linear relation between the breaking strength B and the density.

$$B = B_0 + B_1\rho .$$

One can use these relations to demonstrate a relation between breaking strength B and the velocity of sound v. Since $v = \sqrt{E/\rho}$ it can be shown that the above equations yield

$$B = B_0 + \frac{E_0 B_1}{v^2 - E_1} .$$

Using the values of B_0, B_1, E_0 and E, given by Schryver, it is found that a 15% change in velocity of sound corresponds to a 40% change in breaking strength. Therefore, the observations made and disclosed herein relating the strength of the horse to the velocity of sound are supported by other work on the properties of bone. The link between velocity of sound and bone strength and the required conditions to observe sound propagation in vivo are first disclosed herein.

It was found for present purposes that damping of ultrasonic propagation was so severe at 2×10^6 Hz and at higher frequencies that these frequencies could not be used for a noninvasive measurement of bone strength. Successful experiments were carried out, however, at 500 KHz and 1 MHz. Both acoustic transmission and echo modes are utilized, as will be explained hereinafter.

Cheney et al ("Cannon bone fracture in the thoroughbred racehorse," Med. Biol. Eng. 4:613-620 (1973)) have shown that the force on the cannon bone of a horse may be three to four times the force on the hoof on the ground due to the lever-type action of the fetlock joint. Under a single loading, the breaking strength of the cannon bone in vitro is approximately 71×10^3N. The present model suggests peak forces in the range of 11×10^3N on the hoof, which translates to $33 \times 10^3 \times 10^2$n on the cannon bone. However, Cheney et al have found that repeated loading reduces the strength of the cannon bone by some 40% over a period of 4,000 cycles, which could be produced by 10 races. Similar results have been observed in the tibia of living rats. If this were true of the living system, the breaking strength could drop to 43×10^3N, which is very close to the forces expected from the present model. In the living system, there is a tendency to strengthen bone in the regions of greatest stress. The fatigue weakening of

the bone takes place over a much shorter period than that required for the strengthening process to occur. Consequently, if sufficient recovery time is not allowed for a horse that runs at speeds exceeding his safe speed for a great part of the time, then his supporting bones can be expected to drop in strength to the point where the normal loads experienced in racing will cause fracture. The elastic modulus of bone is known to decrease as it weakens as a result of cyclic loading. The present inventor has discovered that this process can be monitored in the live animal by measuring the velocity of sound across the leg. Measurements on the metacarpal and metatarsal bones at 0.5 MHz and 1MHz, indicate a drop in sound speed across the proximal, distal and midshaft portions of said bones. A drop by 10 percent has been found to exhibit a high correlation with subsequent fracture.

Accordingly, it is an object of the present invention to provide a system for relating the rate of travel of acoustic energy through a bone with the strength of that bone.

Another object is to provide a mechanism to permit in vivo determination of bone strength.

Still another object is to provide a mechanism which permits determination in vivo, of the strength (and changes therein) of leg bones of a quadruped, in particular the horse.

These and still further objects are addressed hereinafter.

The foregoing objects are achieved, generally, in apparatus and method for establishing, in vivo, the strength of a bone (or the condition of tendons, ligaments or the like) that comprises a system for launching an elastic or acoustic pulse through the bone, determining the speed of propagation of the elastic or acoustic energy

through the bone and relating the speed of propagation to the strength of the bone.

The invention is hereinafter described with reference to the accompanying drawing in which:

Fig. 1 is a diagrammatic representation of apparatus to measure the speed of elastic energy in a bone (or tendons or ligaments), in vivo, and shows, diagrammatically a side view of a representation of a portion of a leg of a horse;

Fig. 2 shows, diagrammatically, a portion of the apparatus of Fig. 1; and

Fig. 3 shows, diagrammatically, a modification of the apparatus of Fig. 1.

Turning now to Fig. 1, apparatus to which the general designation A is applied serves to establish, as later discussed in detail, the mechanical strength of a member 1 (which may be a leg bone of a horse, for example, but may also be a tendon or ligament, as later discussed). The bone 1 is surrounded by soft tissue which, for purposes of this explanation, is labeled 2A and 2B to designate, in Fig. 1, tissue at the left of the bone 1 and tissue at the right of the bone 1, respectively. As is noted elsewhere herein, experiments by the present inventor have shown that a substantial change in the elastic properties of the bone 1 affects the transmission speed of sound therethrough. Accordingly, the present inventor determines the speed of sound through the bone and relates that speed and changes therein to the strength of the bone.

Toward this end, the apparatus A includes a launching transducer 3 (also called "first transducer means" herein) having a launching surface 5 and receiving transducer 4 (also called "second transducer means" herein)

having a receiving surface 6. The transducers 3 and 4 are mechanically interconnected by a graduated vernier represented by the broken line marked 7 in Fig. 1 and shown also in Fig. 2. A generation and detection device 8 energizes the transducer 3 to launch an acoustic pulse and receives signals from the transducer 4 when the pulse is received. The device 8 can calculate overall transit time of the acoustic pulse through the bone and surrounding tissue. The present inventor has found that the apparatus A can be employed in a number of ways, as now discussed.

In the live animal, one does not have direct, non-invasive access to the bone. The technique used here is to launch a sound pulse using the launching or sending transducer 3 in Fig. 1 at the surface 15 of the skin of the animal in Fig. 1. This pulse is detected either at another site such as 16 in Fig. 1 on the surface of the leg as a transmitted signal or is detected at the same site 15 as an echo signal, as later noted. Vaseline or other coupling agent is used to effectively couple the sound energy into the leg and also to arch up the transmitted signal through the leg. It has been found that a useful measure of the local strength of the leg in vivo is the effective velocity of propagation through the path starting at the site of the sending transducer through first a covering layer of coat, skin and soft tissue; second the bone itself; and finally the covering layer of coat, skin, and soft tissue at the site of a pick-up transducer 4. The sending and pick-up transducers are held in the vernier apparatus 7 in Fig. 2 that determines the distance between the transducers 3 and 4. In practice the horse is used as his own control and the effective velocity, defined as the distance between sending and pick-up transducers divided by the propagation time, is used as a comparative measure of local bone strength. By comparing the effective

velocities for corresponding regions of the two forelegs or two hind legs, a measure of condition is obtained. It has been found that the effective velocities of sound agree between corresponding sites on a pair of legs to within 1% in normal legs. In abnormal conditions, the effective velocities have been found to be as much as 10% different. In that case, the leg with the lower effective velocity of sound reading has become weakened and there is a danger of severe injury.

Instead of working with the effective velocity, it is possible to determine the actual velocity through the bone by a combination of transmission and echo experiments. First, a transmission measurement is made to determine the effective velocity, i.e., the total transmission time t required for a sound pulse to travel from the launching transducer 3 in Fig. 1 at the skin surface 15 to the skin surface 16 where it is picked up by the receiving transducer 4. The graduated vernier 7 in Fig. 2 measures the total transit distance ℓ between surfaces 15 and 16 of Fig. 1. This measured distance ℓ is the sum of the distances a, b and c shown in Fig. 1, i.e.,

$$\ell = a + b + c.$$

Secondly, echo experiments are made as shown in Fig. 3 at the surfaces 15 and 16 of the leg. A send and receive transducer as 3A in Fig. 3, energized by a pulse generator and receiver 8A, launches an acoustic pulse through the coat and soft tissue 2A of depth b in Fig. 3. This pulse is reflected from the surface 17 of the bone and an echo in Fig. 3 returns to the transducer 3A (at surface 5A) where it is picked up. The time t_1 required for the echo to arrive at transducer 3A is measured. The speed of sound at 1 MHz through the soft tissue of path-length b in Fig. 3 is approximately 1570 m/sec. Denoting this speed as v_t, the distance b in meters is given by

$$b = \frac{1570\ t_1}{2}\ \text{meters}.$$

Repeating this echo experiment at the site 16 where the receiving transducer 4 had been positioned, results in measuring a second echo time t_2 and a determination of the path-length c in Fig. 3:

$$c = \frac{1570\ t_2}{2}\ \text{meters}.$$

The outgoing acoustic pulse and the reflected or echo acoustic pulse in Fig. 3 are indicated by the arrows within the circle marked 10. It should be further noted at this juncture that the transducer 3A can be like the transducers 3 and 4 which can send and receive and the device 8 can be made to interpret both.

The path length a through the bone in Fig. 3 is the measured distance ℓ less b + c. The propagation time t_b through the bone is the total transmission time t defined above, less $(t_1 + t_2)/2$. Hence, the speed of sound through the bone alone denoted by v_b is

$$v_b = \frac{\ell - 785\ (t_1 + t_2)}{t - 0.5\ (t_1 + t_2)}.$$

Measurements of the effective velocity of sound through various parts of the leg or measurements of the actual speed of sound through the bone have been successfully used in a comparative sense, i.e., comparing the sound speed through corresponding regions of a pair of legs. As explained above, differences of 5% or more between corresponding regions is an indication of relative weakness of the leg with the lower effective actual velocity. Not only can measurements be used in a comparative sense but in an absolute sense to measure bone strength. In particular, in young horses, e.g., two-year-olds, one often encounters the condition of bucked shins. Microfracturing of the cannon bone creates a painful condition requiring the horse to be taken out of training.

This microfracturing will be accompanied by a weakening of the bone and a decrease in the effective or actual speed of sound. This ultrasonic method can, therefore, be used to detect the onset of this condition.

Not only can the condition of bone be evaluated by measuring the velocity of sound through the bone but the condition of tendons, ligaments, and other soft tissue can also be determined. A condition known as bowed tendon is common in the horse. It is associated with an overstressing of the deep flexor and superficial flexor tendons. The overstressing leads to mechanical changes in the state of the tendon such as changes in alignment of tendon fibers and fluid invading the tendon structure. These changes will alter the speed and damping of an acoustic signal propagating in the tendon either in a transmission or echo mode. Observation of the speed and damping of the acoustic signal will give information about the condition of the tendon. Comparing the normal and overstressed tendon or ligament is an effective means of determining relative condition.

It has further been observed that the acoustic signal will not propagate across an actual macroscopic fracture. Failure to receive an acoustic signal at the receiving transducer from a sending transducer is a strong indication of actual fracture.

Further modifications of the invention herein disclosed will occur to persons skilled in the art and all such modifications are deemed to be within the scope of the invention as defined by the appended claims.

CLAIMS

1. Apparatus for establishing, in vivo, the strength of bone, that comprises, in combination:

first transducer means having a sending surface to launch an acoustic pulse through the bone and surrounding tissue;

second transducer means having a receiving surface to receive the pulse after transmission through the bone and surrounding tissue;

means to establish with accuracy the separation between the sending surface of the first transducer means and the receiving surface of the second transducer means; and

means to measure the transit time of the pulse from the first transducer means to the second transducer means to permit determination of the effective velocity of the propagated signal.

2. A method of establishing, in vivo, the strength of a leg bone of a quadruped, that comprises:

launching an acoustic pulse through the leg bone;

determining the velocity of propagation of the acoustic energy through the leg bone; and

relating that velocity of propagation to the strength of said leg bone.

3. A method of establishing, in vivo, the relative strength of a leg bone of a quadruped, that comprises:

launching an acoustic pulse through the leg;

receiving the transmitted acoustic pulse;

measuring the distance between the launching site of the pulse and the receiving site thereof;

measuring the time of propagation from the launching site to the receiving site;

determining an effective propagation velocity of the acoustic pulse; and

establishing said relative strength of the leg bone from the propagation velocity.

4. A system for establishing in vivo, the strength of a bone, that comprises means for launching an acoustic pulse through the bone and surrounding soft tissue, and means for determining the speed of propagation of the acoustic energy through the bone and for relating said speed of propagation to the strength of the bone.

5. A method of establishing, in vivo, the strength or condition of a member, that comprises launching an acoustic pulse through the member and surrounding soft tissue; determining the speed of propagation of the acoustic pulse through the member; and relating said speed of propagation to the strength or condition of the member.

6. A method as claimed in claim 5 that includes determining the propagation time of the acoustic pulse in the soft tissue, the total propagation time through the soft tissue and the member, and from the two propagation times thus determined, determining the speed of propagation of the acoustic pulse through the member.

7. A method as claimed in claim 6, wherein the propagation time of the acoustic pulse in the soft tissue is determined using echo techniques wherein the soft tissue comprising a layer of soft tissue at either side of the member which is subjected to acoustic wave energy that passes along a path through the soft tissue to the member which reflects the same to provide an echo pulse that is sensed, the time of travel of the reflected acoustic pulse to and from the member in each layer being used as the basis for determining the time of travel of the pulse through the soft tissue.

8. A method as claimed in claim 7 which further includes determining the total path length along which the acoustic pulse propagates through the two layers of soft tissue and the member, the total path length being used to determine the speed of propagation through the bone.

9. A method as claimed in claim 8, wherein the member is the leg bone of a horse in which the speed of propagation of the acoustic pulse through the leg bone is compared with the speed of propagation of a similar acoustic pulse in the other corresponding leg bone of said horse, and the strength of each leg bone is assessed on the basis of that comparison.

10. A method as claimed in claim 9, wherein the assessment of the strength of each said leg bone is made on the basis that a difference in speed of propagation of the acoustic pulse through one said leg bone from the speed of propagation of the acoustic pulse through the other leg bone of greater than about five percent indicates a weakness in the leg bone in which the acoustic pulse propagated at the slower speed.

11. A method of evaluating the condition of a tendon or ligament that comprises launching an acoustic pulse into the tendon or ligament, measuring the time required for the transmission from the launching site to a pick-up site, measuring the path length for the acoustic pulse, determining a speed of propagation from said time and said path length, and relating said speed of propagation to the physical condition of the tendon or ligament.

12. A method as claimed in claim 11, wherein the launching site and pick-up site are distinct sites and the mode of propagation is transmission between said sites.

13. A method as claimed in claim 11 wherein the launching site and pick-up site are the same site and the mode of propagation is an echo mode.

FIG. 1

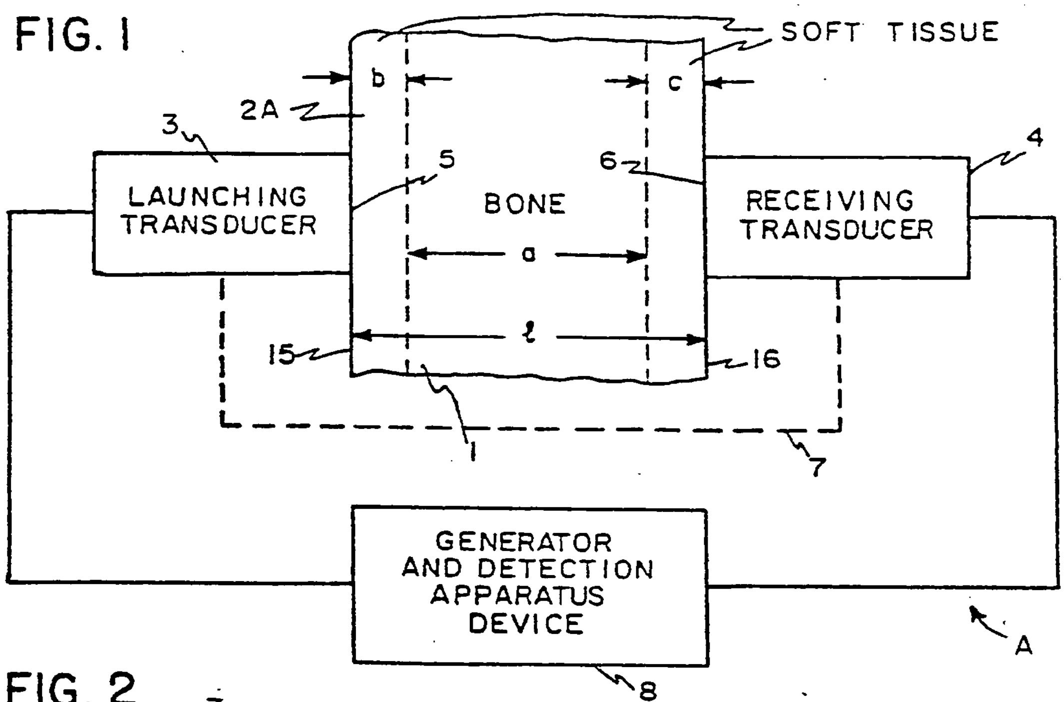


FIG. 2

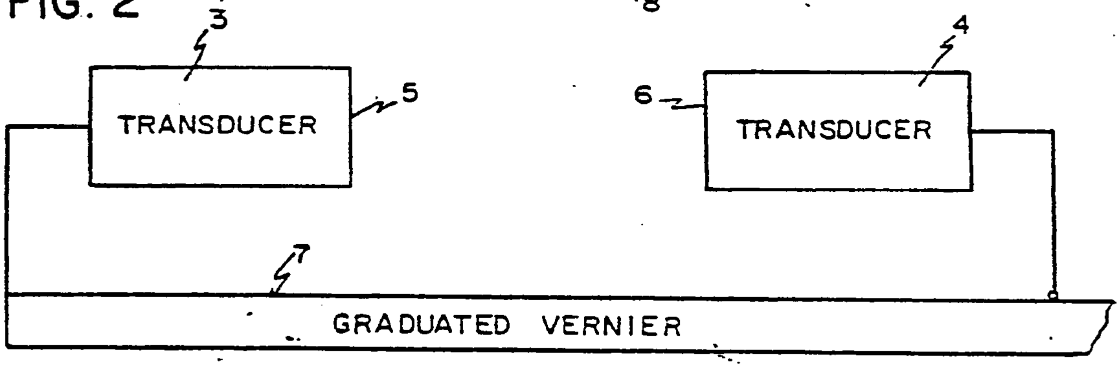
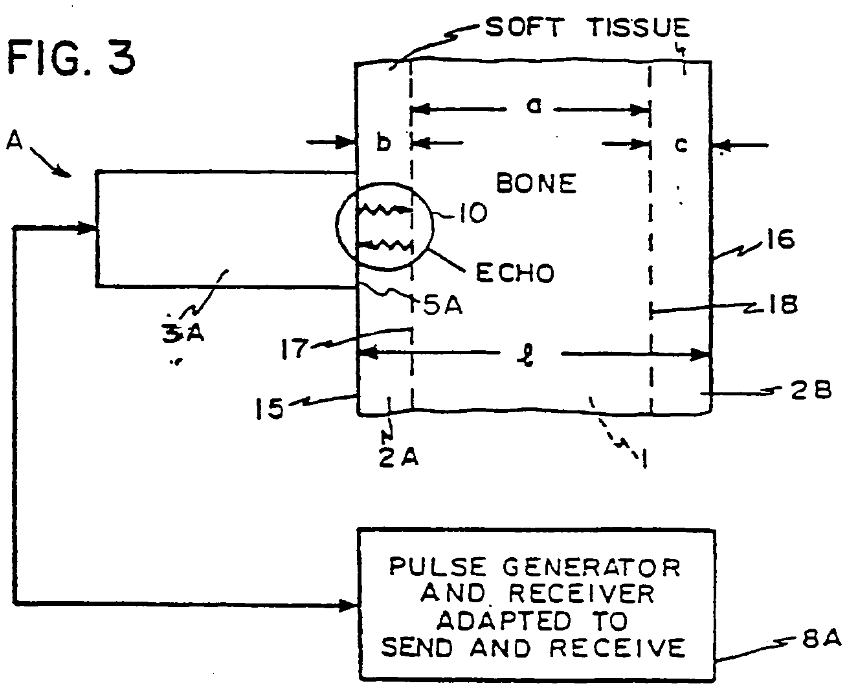


FIG. 3



INTERNATIONAL SEARCH REPORT

International Application No: PCT/US80/00744

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int. Cl3 A61B 10/00
U.S. Cl. 128/660

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
U.S.	128/660,630 73/597,598,632

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
X	US, A, 2,439,130, Published 06 April 1948 Firestone	1 and 4
X	US, A, 3,847,141, Published 12 November 1974 Hoop	1 and 4
A	US, A, 4,048,986, Published 20 September 1977 Ott	2,3 and 5-13
A	US, A, 3,477,422, Published 11 November 1969 Jurist, Jr. et al	2,3 and 5-13
A	US, A, 3,664,180, Published 23 May 1972 McDonald et al	1 and 4
A	US, A, 3,713,329, Published 30 January 1973 Munger	2,3 and 5-13
A	SU, A, 219853, Published 02 September 1968 Sergienko	1 and 4

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"T" later document published on or after the international filing date or priority date and not in conflict with the application, but cited to understand the principle or theory underlying the invention

"X" document of particular relevance

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
11 September 1980	02 OCT 1980
International Searching Authority [1]	**Signature of Authorized Officer** [20]
ISA/US	Kyle L. Howell

Form PCT/ISA/210 (second sheet) (October 1977)

See note -

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FIG. 1

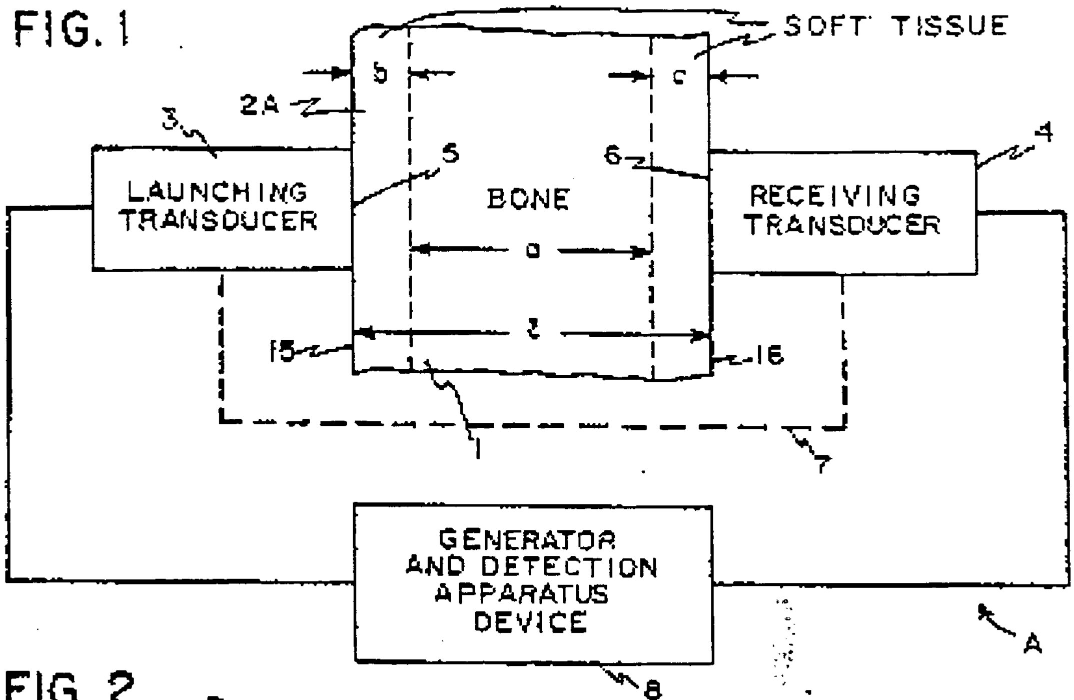

FIG. 2

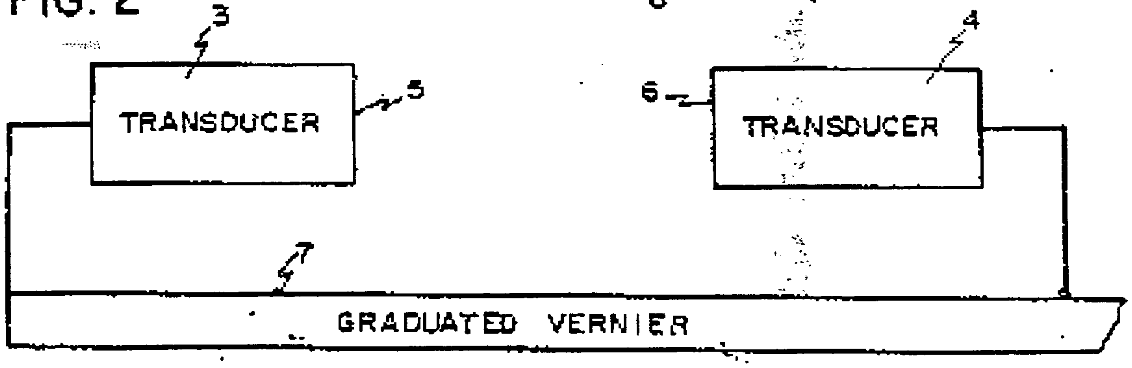

FIG. 3